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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,277	08/20/2001	Peter Jozef Leo Hespel	702-010802	6608

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EXAMINER	
GOLLAMUDI, SHARMILA S	
ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 01/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/856,277	HESPEL, PETER JOZEF LEO	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Amendment B and request for Extension of time received on October 29, 2002, are acknowledged. Claims 9-20 are included in the prosecution of this application.

Claim Rejections - 35 USC § 112

Rejection of claims 9 and 13 under 35 U.S.C. 112, first paragraph are withdrawn in view of arguments.

Claim Rejections - 35 USC § 102

Rejection of claims 9-11, 13-14, and 16-17 under 35 U.S.C. 102(b) as being anticipated by JP 08224073, is maintained. New claims 19-20 are also rejected.

JP teaches a creatine (1-3g) drink for muscle fatigue or as a nutrition drink. The reference does not teach any addition exercising to in increase muscle capacity. (Note abstract)

Response to Arguments

Applicant argues that JP teaches a drink that can be given to individuals suffering from mere muscle fatigue after undergoing physical strain. It is argued that instant invention discloses the therapeutic preparation for treating immobilized muscles not strained ones.

Applicant's arguments have been fully considered but they are not persuasive. Firstly, the examiner points out that claims 9-11 are composition claims and the intended use of instant preparation, i.e. for preventing or treating muscle disuse, does not hold patentable weight. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in

order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

In regards to claims 13-18, the examiner points to page 1 of instant specification in which the applicant teaches symptoms of muscles disuse include premature muscle fatigue and as recognized by the applicant, JP discloses the use of the drink to recover from muscle fatigue. Therefore, since JP clearly teaches treating a known symptom of muscle disuse, JP anticipates instant invention.

Rejection of claims 9-11, 13-14, 16, and 18 under 35 U.S.C. 102(b) as being anticipated by XP-00210314, is maintained. New claims 19-20 are also rejected.

XP teaches an oral creatine supplement for alleviating muscle weakness and degeneration caused by diseases (Note abstract and pg. 334, first paragraph).

Response to Arguments

Applicant argues that XP teaches the use of an oral supplement for alleviating muscle weakness and degeneration of muscles caused by muscle weakness. It is argued that muscle disuse is related to muscular disease only in that muscular disease may be associated with reduced mechanical loading caused by muscle disease, etc.

Applicant's arguments have been fully considered but they are not persuasive. As discussed above, intended use for composition claims do not hold patentable weight. Secondly, it is the examiner's position that since XP is treating muscle weakness and

restoring function, it is inherently treating muscle disuse by allowing the muscles to regain use. Additionally, page 1 of instant specification teaches muscle disuse syndrome is defined as degeneration of muscles and symptoms include muscle atrophy, fatigue, etc. Further, specification states muscle disuse syndrome may occur in any skeletal muscle subject to reduce reduced mechanical loading due to whatever cause and that mechanical unloading may occur due to disease condition and any other condition associated with a reduced level of physical activity." Therefore, XP is clearly treating muscle disuse syndrome.

Claims 9-11, 13, and 15-18 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0222257. New claims 19-20 are also rejected.

EP teaches a phosphocreatine composition for treating muscular atrophy and dystrophy (col. 1, lines 4-7). The formulation contains 1g of phosphocreatine (Note example 3).

Response to Arguments

Applicant argues that EP teaches a parenteral administration to treat muscular atrophy and dystrophy. Instant invention is orally administered as a drug or nutritional supplement.

Applicant's arguments have been fully considered but they are not persuasive. The examiner points out that instant claims do not recite the therapeutic preparation in the form of an oral dosage form. The dependent claims merely recite the preparation which is a drug and a nutritional supplement. Nutritional supplements are not necessarily in the form of oral dosage forms. Secondly since a structural limitation is not

recited in the instant claims, the intended use of a composition claims such as an oral versus parenteral, does not hold patentable weight. Lastly, as discussed above, clearly instant specification teaches that one of the symptoms of muscle disuse is muscle atrophy; therefore since EP is capable of treating the symptoms of instant syndrome, it is treating the syndrome itself.

Rejection of claims 9-11 under 35 U.S.C. 102(b) as being anticipated by Almada et al (5627172), is maintained. <u>New claim 19 is also rejected.</u>

Almada et al teach an oral composition containing at least one creatine derivative (Note abstract). The reference discloses prior art in which creatine or its derivatives are used to treat muscular dystrophy. The creatine derivatives are administered in an amount of 1 to 30 grams a day (col. 3, lines 58-59). Further, the creatine or its derivatives can be administered in tablets, powders or candy bars (col. 4, lines 1-7 and lines 35-40).

Response to Arguments

Applicant argues that Almada teaches creatine as ergogenic aids and taken by healthy individuals in contrast to instant invention.

Applicant's arguments have been fully considered but they are not persuasive. The examiner points out that only the composition claims are rejected and as set forth above, intended use does not hold patentable weight.

Claim Rejections - 35 USC § 103

Rejection of claim 12 under 35 U.S.C. 103(a) as being unpatentable over Almada et al (5627172) is maintained.

Almada et al teach an oral composition containing at least one creatine derivative (Note abstract and col.2, lines 15-19). The reference discloses prior art in which creatine or its derivatives are used to treat muscular dystrophy. The creatine derivatives are administered in an amount of 1 to 30 grams a day (col. 3, lines 58-59). Further, the creatine or its derivatives can be administered in tablets, powders or candy bars (col. 4, lines 1-7 and lines 35-40).

Almada et al do not provide a specific example treating the instant syndrome or an example in which more than one creatine compound is used in food.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use more than one creatine compound as suggested by the reference. One would be motivated to do so with the expectation of at least an additive effect. Further, it is deemed obvious to use Almada's composition to treat muscle disuse since Almada teaches prior art in which creatine in used to treat this muscular disorders.

Response to Arguments

Applicant argues that Almada teaches creatine as ergogenic aids and taken by healthy individuals in contrast to instant invention.

Applicant's arguments are persuasive in regards to the method claims and rejection of these claims are withdrawn. However, rejection claim 12 is maintained since claim 12 is a composition claim and Almada clearly teaches the use of one or more creatine derivatives in a dosage form such as a candy bar.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 703-305-2147. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 709-3080196.

SSG

January 2, 2003

MICHAEL G. HARTLEY
PRIMARY EXAMINER